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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/689,866 | 10/21/2003 | Benjamin Oshlack | 200.1133CON | 3333 |

7590 01/26/2007

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New York, NY 10018

| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |
| ART UNIT | PAPER NUMBER |
| 1615 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 01/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/689,866 | BENJAMIN OSHLACK ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/02/04; 06/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Information Disclosure Statements (IDS) filed 09/02/04 and 06/13/06 is acknowledged.

Claims 1-61 are pending in this action. Claims 1-61 are rejected.

### *Inventorship*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-73 of copending Application No. 10/700,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant '866 application and the copending '861 application.

Namely, both applications claim an opioid agonist, an opioid antagonist and hydrophobic materials (sequestering material). It is noted that claim 24 of the instant '866 application claims hydrophobic materials, such as cellulose or acrylic polymers. It is also noted that claim 72 of the copending '861 application claims hydrophobic materials, such as cellulose or acrylic polymers.

The only distinctions observed between the instant '866 application and the copending '861 application is that the instant '866 application claims the recitation of specific release rates and/or ratios whereas the '861 application does not claim specific release rates and/or ratios. Also, the instant '866 application claims the non-isolation of agonist and antagonist whereas the copending '861 application has a layered structure. Asides from these distinctions, the inventions of each application are quite similar.

While the copending '861 application does not claim the specific ratios as is claimed by the instant '866 application, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is

evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable ratios and/or amounts by routine or manipulative experimentation to obtain optimal results as these are variable parameters and the copending '861 application teaches a similar pharmaceutical composition comprising similar components for use in the same field of endeavor as that desired by Applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-74 of copending Application No. 10/700,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because similar subject matter has been claimed in both the instant '866 application and the copending '906 application.

Namely, both applications claim an opioid agonist, an opioid antagonist and hydrophobic materials (sequestering material). It is noted that claim 24 of the instant '866 application claims hydrophobic materials, such as cellulose or acrylic polymers.

The only distinctions observed between the instant '866 application and the copending '906 application is that the instant '866 application claims the recitation of specific release rates

and/or ratios whereas the '906 application does not claim specific release rates and/or ratios. Also, the instant '866 application claims the non-isolation of agonist and antagonist whereas the copending '906 application has a layered structure. Asides from these distinctions, the inventions of each application are quite similar.

While the copending '906 application does not claim the specific ratios as is claimed by the instant '866 application, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine suitable ratios and/or amounts by routine or manipulative experimentation to obtain optimal results as these are variable parameters and the copending '906 application teaches a similar pharmaceutical composition comprising similar components for use in the same field of endeavor as that desired by Applicants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Pertinent Art***

Prior Art made of record and cited of interest:

- Chen *et al.* – U.S. Patent No. 4,573,995

Chen *et al.* teach a delivery system comprising opioid antagonists (i.e., naloxone, naltrexone) dispersed in a matrix of hydrophobic materials (see Abstract and column 2).

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

Primary Examiner

Art Unit 1615

January 21, 2007

*hns*